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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,005	09/11/2000	Erich Wanker	V0179/7001	1379
7590 08/26/2008				
Helen C Lockhart Wolf Greenfield & Sacks Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			EXAMINER GABEL, GAILENE	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 08/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/485,005

**Applicant(s)**

WANKER ET AL.

**Examiner**

GAILENE R. GABEL

**Art Unit**

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8-20 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-16 and 31-41 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-12, 17-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-883)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and response filed on May 12, 2008 is acknowledged and has been entered. Claims 1 and 13 have been amended. Currently, claims 1-5, 8-20, and 27-41 are pending and are under examination.

### ***Withdrawn Rejections***

2. All rejections not reiterated herein, have been withdrawn
3. In light of Applicant's amendment, the rejection of claims 1-5, 8-20, and 27-41 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.
4. In light of Applicant's amendment, the rejection of claims 1-5, 8-12, 17-20, and 27-30 under 35 U.S.C. 103(a) as being unpatentable over Notario et al. (Changes in the membrane proteins of blood cells in the course of embryonal megalocerythropoiesis in relation to hemoglobin maturation) Archivio per le scienze mediche, 135 (1): 1-8 (1978 Jan-Mar) Abstract) in view of Tanzi et al. (US Patent 6,365,414), is hereby, withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 8-12, 17-20, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanzi et al. (US Patent 6,365,414) in view of Selkoe et al. (Alzheimer's Disease: Insolubility of Partially Purified Helical Filaments in Sodium Dodecyl Sulfate and Urea; Science 215: 1243-1245 (1982)).

Tanzi et al. disclose an in vitro system for determining formation of A $\beta$  amyloid which occurs in A $\beta$  amyloidotic disorders such as Alzheimer's disease. Alzheimer's disease is known to be associated with multiple polyglutamine expansions (Abstract). Specifically, Tanzi et al. teach filtering a biological sample which contains A $\beta$  amyloid fibrils on cellulose acetate membrane or nitrocellulose filters (col. 8, lines 18-33 and col. 9, lines 31-37 and lines 54-61). Amyloid fibrils are retained on the filter and stained with amyloid staining dye such as Congo Red so as to be detected using electron microscopy (col. 9, line 66 to col. 10, line 28 and lines 50-56). Tanzi et al. specifically

teach the importance of using a filter having appropriate pore size that retains amyloid fibrils and aggregates thereof by preventing their passage through the filter and allows passage of solubilized amyloid peptides (col. 11, lines 48-63).

Tanzi et al. differ from the instant invention in failing to teach pre-treating a sample with urea or detergent such as sodium dodecyl sulfate (SDS) to determine insolubility of the amyloid-like fibrils or aggregates.

Selkoe et al. teach subjecting biological samples of Alzheimer's Disease (AD) patients to urea and SDS and found that certain amyloid-like fibrils and protein aggregates (partially purified helical filaments) present in the sample are insoluble to urea and detergent (pp. 1243-1244, especially p. 1244, cols. 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to pre-treat samples suspected of containing amyloid like fibrils and proteins aggregates such as those obtained from AD patients, with urea or SDS detergent such as taught by Selkoe, prior to filtering, capturing, and determining the presence of the insoluble amyloid fibrils and protein aggregates using the method of Tanzi, because Tanzi specifically taught that amyloid-like fibrils are highly insoluble and Selkoe confirmed such high insolubility by treatment with urea and SDS, and Tanzi taught that nitrocellulose membrane and cellulose acetate filters are capable of capturing and retaining insoluble amyloid fibrils and protein aggregates. Additionally, Tanzi specifically provided that cellulose acetate membranes are conventional filters

known in the art advantageously known for their capability to separate, capture, and isolate large amyloid fibrils and aggregated proteins.

***Response to Arguments***

6. Applicant's arguments filed on May 12, 2008 have been fully considered but are moot in light of the new grounds of rejection.

***Allowable Subject Matter***

7. Claims 13-16 and 31-41 are free of the prior art of record.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

August 20, 2008